

REMARKS

With entry of this amendment, claims 23-30 are under examination. Support for new claims 29 and 30 can be found throughout the specification, for example at paragraphs 35 and 36. No new matter has been added. Reconsideration is requested.

Claims 23-25, 26 and 28 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. This rejection is traversed for the following reasons.

The Examiner states that the claims are inclusive of a genus of compositions that bind to a genus of cell surface proteins or carbohydrates and takes the position that the written description only sets forth a composition comprising an anti-transferrin receptor antibody avidin conjugate. Applicants respectfully submit that the specification fully describes a variety of possible targeting moieties and receptors, for example, at page 6 in paragraph 32, wherein numerous receptor ligands and receptors are listed. It is respectfully submitted that those of skill in the art would be able to make and test cytotoxic agents consisting of a targeting moiety and an avidin moiety, for example, insulin, epidermal growth factor, insulin like growth factor, erythropoietin, neurotrophic factor 3, etc. bound to, for example, avidin, streptavidin neutravidin, etc., as described in paragraph 33. The means for making and testing such compositions are known in the art, and would not require undue experimentation.

Claims 23-28 have been rejected under 35 USC § 102(b) as being anticipated by Penichet et al. This rejection is traversed for the following reasons.

Penichet et al. teaches an Antibody-avidin fusion protein in combination with a biotinylated compound for the purpose of delivering biotinylated compounds across the blood brain barrier. In contrast, the compositions of the present invention cause apoptosis and cell death. Furthermore, the presence of biotin is specifically excluded from the compositions of the present invention (see, *e.g.*, paragraph 11 of the specification).

Penichet et al. do not teach or suggest a composition comprising a cytotoxic agent consisting of a targeting moiety and an avidin moiety wherein said targeting moiety is

capable of binding to one or more of said cell surface proteins or carbohydrates in combination with a pharmaceutically acceptable carrier. It is respectfully pointed out that the present claims exclude any pharmaceutical compositions of Penichet et al. by the use of "consisting of" in describing the cytotoxic compound.

For all of these reasons, it is respectfully submitted that Penichet et al. does not anticipate the presently pending claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 23-28 have been rejected under 35 US § 102(b) as being anticipated by WO 01/07084. This rejection is traversed for the following reasons.

WO 01/07084 teaches a fusion protein for the delivery of a wide variety of agents to a cell via antibody-receptor mediated endocytosis comprising a variable region of an antibody and a protein that can be avidin, *inter alia*. However, this document does not teach that this fusion protein would be useful, without more, as a pharmaceutical composition. Rather, it teaches its use in combination with additional agents to target biotin linked compounds to cells. The compounds disclosed undergo antibody-receptor-mediated endocytosis to deliver the attached cargo (biotin-linked compounds) to cells (see, e.g. page 6, first paragraph). The present application describes and claims cytotoxic agent consisting of a targeting moiety and an avidin moiety in combination with a pharmaceutical carrier. In contrast to the prior art, cells to which the claimed composition is administered undergo apoptosis and cell death. Furthermore, the presence of biotin is specifically excluded from the compositions of the invention (see, e.g., paragraph 11 of the specification). There is nothing in WO 01/07084 that discloses the presently claimed pharmaceutical composition, or suggests that it would be useful.

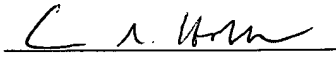
For all of these reasons, it is respectfully submitted that the present claims are not anticipated by WO 01/07084. Reconsideration and withdrawal of the rejection are respectfully requested.

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All rejections having been addressed, it is respectfully submitted that the application is in condition for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted,

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